Department of
AGRICULTURE
FISHERIES &
FORESTRY –
AUSTRALIA

Import Risk Analysis Handbook

Canberra, 2003

Preferred way to cite this publication:

Biosecurity Australia 2003, Import risk analysis handbook, Agriculture, Fisheries and Forestry– Australia, Canberra

ISBN 0-97504-730-2

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If you experience problems accessing the file on the website or wish to obtain a hard copy, please contact:

Biosecurity Development and Evaluation
Biosecurity Australia
GPO Box 858
CANBERRA ACT 2601
Telephone: +61 2 6272 4914
Facsimile: +61 2 6272 4568
E-mail: bde@affa.gov.au

Contents

The import risk analysis flowchart has been reproduced on the inside back cover to assist readers.

1. Purpose

This *Import Risk Analysis Handbook* sets out the process that Biosecurity Australia follows to undertake an Import Risk Analysis (IRA).

The handbook builds on the 1998 *AQIS Import Risk Analysis Process Handbook* that was part of the Government response to recommendations of the Australian Quarantine Review Committee[1]. The revisions to the process are based on Biosecurity Australia's experience with Import Risk Analysis, the results of relevant parliamentary reviews, advice from the Quarantine and Exports Advisory Council (QEAC) and comments from stakeholders.

[1]The Australian Quarantine Review Committee's report was issued in 1996 and is also referred to as the Nairn Report after its chairperson.

2. Biosecurity policy

2.1 Australia's biosecurity policy

2.1.1 Objectives

The objective of the Australian biosecurity policies referred to in this handbook is the prevention or control of the entry, establishment or spread of pests and diseases that will or could cause significant damage to human beings, animals, plants, other aspects of the environment, or economic activities.

Biosecurity Australia develops biosecurity policies for matters that fall under the responsibility of the Department of Agriculture, Fisheries and Forestry – Australia (AFFA)[2].

Australia has unique and diverse flora and fauna, has valuable agricultural industries and is relatively free from serious pests and diseases. Therefore, successive Commonwealth Governments have maintained a conservative but not a zero-risk approach to the management of biosecurity risks. This approach is consistent with the World Trade Organization *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement) and is evident in the range of biosecurity related activities, including policies on imported commodities, procedures at the border, and operations against incursions of pests and diseases.

The SPS Agreement (see Annex 8) defines the concept of an 'appropriate level of sanitary or phytosanitary protection (ALOP)' as the level of protection deemed appropriate by a WTO Member in establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. In setting its ALOP, a WTO Member should take into account the objective of minimising negative trade effects.

Like many other countries, Australia expresses its ALOP in qualitative terms. Australia's ALOP, which reflects community expectations through government policy, is currently expressed as providing a high level of sanitary or phytosanitary protection aimed at reducing risk to a very low level, but not to zero.

2.1.2 Risk management and SPS measures

Australia's plant and animal health status is maintained through the implementation of measures to facilitate the importation of products while protecting the health of people, animals and plants.

Australia's approach to addressing requests for imports of animals, plants and their products, where there are biosecurity risks, is to draw on existing sanitary and phytosanitary measures for similar products with comparable risks. However, where measures for comparable biosecurity risks have not previously been established, a thorough assessment will be necessary to identify the risks to Australia and determine what sanitary and phytosanitary measures are needed to reduce those risks to a level consistent with Australia's ALOP.

[2] Primary policy responsibility for human biosecurity, including food safety, rests with the Department of Health and Ageing.

2.2 Biosecurity Australia

Biosecurity Australia is part of the Commonwealth Department of Agriculture, Fisheries and Forestry – Australia (AFFA). It was established as an entity separate from the Australian Quarantine and Inspection Service (AQIS) in October 2000 to distinguish biosecurity policy development and export technical market access negotiations from the operational work of AQIS. AQIS's responsibilities include ensuring border quarantine security, issuing import permits and providing export health certification.

Biosecurity Australia is responsible for:

- developing new biosecurity (sanitary and phytosanitary) risk management measures and reviewing existing measures for the importation of live animals and plants, and animal and plant products
- working with AQIS on the implementation of biosecurity measures
- conducting technical negotiations with counterpart agencies in other countries, to develop new market access and maintain and improve upon existing market access for Australian live animals and plants, their genetic material and plant products
- participating in the activities of the international standard-setting organisations relevant to biosecurity
- working with various Commonwealth and State/Territory organisations in relation to the continuum of quarantine.

Biosecurity Australia has considerable experience in import risk analysis. Its work on import risk analysis also involves experts from bodies such as relevant State and Territory agencies, the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and universities.

As part of import risk analysis, Biosecurity Australia, works in partnership with the States and Territories to address regional differences in pest status and risk within Australia, and consequent sanitary and phytosanitary measures. This involves consultation with relevant State and Territory agencies throughout the course of an import risk analysis (IRA), with an emphasis on identifying and resolving issues relating to regional differences in pest status and risk early in the IRA process.

2.3 Australian legislation

The Australian quarantine system is supported by Commonwealth, and State and Territory quarantine laws. Under the Australian Constitution, the Commonwealth Government does not have exclusive power to make laws in relation to quarantine, so Commonwealth and State laws on quarantine co-exist. However, under section 109 of the Constitution, if a State law is inconsistent with a Commonwealth law, the Commonwealth law prevails and the State law is invalid to the extent of the inconsistency.

Protection of Australia's human, animal and plant life requires the application of controls, established by the Commonwealth, at Australia's international borders. Commonwealth quarantine laws are contained in the *Quarantine Act 1908* and in its subordinate legislation found in the *Quarantine Proclamation 1998* and the *Quarantine Regulations 2000*.

Responsibility for human health under the *Quarantine Act 1908* rests with the Department of Health and Ageing. Biosecurity Australia regularly consults with that Department. The Quarantine Act requires the Director of Animal and Plant Quarantine to ensure that environmental factors are considered in the decision making process. A Memorandum of Understanding (MOU) is in place between Biosecurity Australia and Environment Australia to facilitate input of advice on environmental matters into the import risk analyses.

2.4 International agreements and standards

The process set out in this Handbook conforms to Australia's international obligations. These derive, inter alia, from the SPS Agreement and other World Trade Organization (WTO) Agreements and specific international guidelines and standards on risk analysis developed under the International Plant Protection Convention (IPPC) and by the Office International des Epizooties (OIE— the World Organization for Animal Health).

Australia bases its national measures on international standards where they exist and where they deliver the appropriate level of protection from pests and diseases. However, where such standards are not appropriate to Australia's level of biosecurity protection, or relevant standards do not exist, Australia exercises its right under the SPS Agreement to impose appropriate measures, justified on scientific grounds and supported by risk analysis.

The procedures described in this Handbook are consonant with Australian/New Zealand Standards AS/NZS 3931:1998 (*Risk analysis of technological systems—application guide*) and AS/NZS 4360:1999 (*Risk management*).

2.5 Notification obligations

Under the transparency provisions of the SPS Agreement, WTO members are required to notify other members through the WTO secretariat of proposed new sanitary or phytosanitary regulations, or changes to existing regulations, that are not substantially the same as the content of an international standard and that may have a significant impact on international trade, at a stage when any comments can be taken into account. Australia's practice is to notify Draft IRA reports and to allow a 60-day period for comment. Australia also notifies to the WTO the outcome of the IRA process.

3. Administrative process for Import Risk Analysis

3.1 What is Import Risk Analysis

In animal and plant biosecurity, import risk analysis identifies the pests and diseases relevant to an import proposal, assesses the risks posed by them and, if those risks are unacceptable, specifies what measures should be taken to reduce those risks to an acceptable level. These analyses are conducted via the administrative process described in this Handbook.

3.2 How the Process is started

Biosecurity Australia may initiate development of new biosecurity policy or review an existing policy in response to:

- a proposal to import a plant, an animal, a good derived from plants or animals, a micro-organism, or commodities which present a biosecurity risk
- the identification of a changed risk profile or the receipt of new information by Biosecurity Australia or AQIS, or
- an application to AQIS for an import permit.

Proposals and applications may come from individuals, companies, organisations, government agencies or governments (both in Australia and overseas).

Where it is apparent that the biosecurity risks associated with an import proposal or application are similar to those addressed by an existing policy, an IRA may not be considered necessary.

3.3 When are IRAs undertaken?

Following from the situations described in 3.2 above, Biosecurity Australia may undertake an IRA if:

- there is no relevant existing biosecurity measure for the good and pest/disease combination; or
- a variation in established policy is desirable because pests or diseases, or the likelihood and/or consequences of entry, establishment or spread of the pests or diseases could differ significantly from those previously assessed.

3.4 Function of the handbook

This handbook sets out the process supporting the Government's biosecurity objectives, including:

- biosecurity measures based on sound science

- alignment of accepted risks with Australia's ALOP
- biosecurity measures which comply with Australia's domestic legislation and international obligations.

3.5 Variation of the Process

In circumstances where there is a significant change in the basis for an IRA, such as development of a new relevant international standard, the Executive Manager of Biosecurity Australia may determine that the conduct of an IRA should be varied. Biosecurity Australia may terminate an IRA at any stage on its own initiative or if a proponent/applicant requests that it be terminated.

There will be occasions when variation of the administrative procedures in this handbook is necessary. Stakeholders are informed of such circumstances and the actions taken as soon as practicable. See Annex 4 for appeal rights.

3.6 Economic issues

In keeping with the scope of the *Quarantine Act 1908* (see Sections 2.2 and 3.1 of this handbook) and Australia's obligations as a member of the WTO, economic considerations are taken into account only in relation to matters arising from the potential direct and indirect impact of pests and diseases that could enter, establish or spread in Australia as a result of importation.

The potential competitive economic impact of prospective imports on domestic industries is not within the scope of IRAs.

3.7 Biosecurity Australia: internal methodologies

Biosecurity Australia has internal processes to assist those conducting Import Risk Analysis work. These include the production of a technical manual on the methodologies available for the conduct of IRAs, called the *Guidelines for Import Risk Analysis*. The structured approach described in these Guidelines is consistent with Australian legislation and Government policy, the requirements of the WTO SPS Agreement, and the relevant international plant and animal health standards developed under the IPPC and by the OIE.

3.8 Communication with stakeholders

Biosecurity Australia maintains a register of stakeholders to assist effective consultation and communication. Stakeholders comprise government agencies, individuals, community or industry groups or organisations, in Australia or overseas, including the proponent/applicant for a specific proposal, having an interest in the subject matter of an IRA.

The register (see Annex 5) enables stakeholders to indicate the IRAs in which they are interested, and the way they prefer to receive information. However, if a person or organisation chooses not to be placed on the stakeholder register, they may access information on the IRA work program and on the status of IRAs through

the Biosecurity Australia website: www.affa.gov.au/biosecurityaustralia.

Copies of completed IRAs and other IRA documents are available on the website.

3.9 Public file

At the commencement of each IRA, Biosecurity Australia establishes a public file to contain non-confidential submissions and other technical documentation. Each public file is held at Biosecurity Australia's office in Canberra. Documents may be accessed by appointment during business hours for perusal and copying, and information in electronic form is available to stakeholders on request. Stakeholders are encouraged to make submissions electronically to assist in maximising access to documents.

Further details of the material to be placed on each public file are in Annex 6.

3.10 Other assessment processes

This handbook does not describe procedures used to assess animals or plants for their potential to become pests, or organisms imported as biological control agents, or the evaluation of traits conferred on a plant or animal species by genetic manipulation. Information on methodology and procedures for these assessments is available from Biosecurity Australia (see Annex 1 for contact details).

Under the *Environment Protection and Biodiversity Conservation Act 1999*, Environment Australia may assess proposals for the importation of live specimens and their reproductive material. Such an assessment may be used or referred to by Biosecurity Australia in its analyses.

4. Steps in Import Risk Analysis

The flowchart at Annex 7 summarises the sequence of the steps set out here.

Initiation

1. Submission of import proposals

Requests for market access may be submitted directly to Biosecurity Australia (usually by the relevant government authorities of the country seeking to export), or may arise as the result of an application to AQIS for an import permit.

2. Policy development or review initiated by Biosecurity Australia

Biosecurity Australia may initiate the development or review of policy, for example, where there are changed risk profiles or upon the receipt of new information by Biosecurity Australia or AQIS.

Scheduling and scoping

3. IRA work program

Biosecurity Australia examines proposals to determine which ones require an IRA. Many proposals will not require an IRA to be conducted. Those requiring an IRA will be scheduled, taking into account factors such as the resources available (Biosecurity Australia staff as well as suitably qualified external experts); the complexity of the IRA (e.g. the number and type of pests and diseases that need to be considered); the availability of information necessary to support the analysis; and the quality, completeness and timing of responses by the proponent country to requests for information. Biosecurity Australia seeks to address proposals from the same country in the order preferred by that country.

Biosecurity Australia routinely advises stakeholders about its IRA work program via e-mail, letter, the website and *Biosecurity Australia News*. This advice describes the status of IRAs currently underway and those that Biosecurity Australia expects to commence in the near future. Provision is made for changing priorities, research needs and resource constraints. Biosecurity Australia welcomes stakeholder comments at any time on its work program and priorities.

At the time a proposal or application requiring an IRA is lodged, it need not contain the detail required for Biosecurity Australia to commence work. However, before a specific risk analysis is commenced, Biosecurity Australia may seek more information from the proponent, including technical information to confirm the purpose and scope of the proposal.

4. Consultation with States, Territories and other Commonwealth agencies

States and Territories have a special role in policy development, flowing from their responsibilities for managing animal and plant health within Australia. There is a partnership approach to managing risks, both for the movement of product into Australia or for trade within Australia. The 1995 Memorandum of Understanding (MOU) between the Commonwealth and States/Territories on Animal and Plant Quarantine Measures records the parties' commitments. The partnership approach is particularly important in the IRA process, because close cooperation at all stages of an IRA is needed to ensure that information pertinent to a specific State or Territory is considered in the national risk analysis.

Biosecurity Australia therefore works closely with relevant State and Territory agencies on the IRA work program and on arrangements for IRAs about to commence. This reflects the MOU and the continuum of responsibilities for biosecurity. For particular IRAs, the scope, the likely risks, and the expertise that may be required to address those risks will also be discussed. The States and Territories may identify specific technical issues that they believe should be considered during an IRA, including regional differences in pest and disease status and risk, and may nominate officers with relevant expertise who could participate in the IRA.

Biosecurity Australia works closely with Environment Australia on issues relevant to that portfolio. Biosecurity Australia also consults with other Commonwealth agencies where they have responsibilities relevant to the IRA, e.g. Food Standards Australia New Zealand (FSANZ) and the Department of Health and Ageing.

5. Scope, approach and IRA Team membership

An IRA team conducts each IRA. Membership of the team is governed by the availability the required technical expertise within Biosecurity Australia and, if necessary, the extent to which expertise outside Biosecurity Australia may be required. For all IRAs, the IRA team is chaired by a senior official from Biosecurity Australia or a related group in AFFA. It is important that IRA team members do not have vested interests in relation to the IRA, that they are able to exercise sound scientific judgement, and that the process is objective and seen to be objective.

Details of the terms of reference, operating procedures and considerations on membership for IRA Teams are at Annex 2.

Biosecurity Australia provides administrative and secretarial support for IRA teams.

Biosecurity Australia determines the intended scope of the IRA with the proponent/applicant, that is, the goods to be assessed and the source (zone or country or countries of origin). The goods and source(s) need to be defined to allow an accurate list of relevant pests and diseases to be drawn up for categorisation. Biosecurity Australia may determine that, for reasons of efficiency or to address related proposals or applications, the scope of the IRA should be varied to include or exclude other commodities and/or other sources.

Biosecurity Australia may decide to involve third parties to assist in conducting IRAs. In such cases, Biosecurity Australia assesses the documents produced by a third party, their scientific basis, and whether they conform to the Government's objectives for biosecurity.

6. Initial consultation with registered stakeholders

When work on an IRA is about to commence, Biosecurity Australia consults with registered stakeholders via a memorandum that includes:

- the proposed scope and approach of the IRA
- the required expertise
- where appropriate, an invitation for nominations for external membership of the IRA team.

The information is placed on the Biosecurity Australia website.

Stakeholders have 30 days after the memorandum is issued to provide comments and membership nominations to Biosecurity Australia. Submissions received are placed on the public file created for the IRA unless a request for confidentiality is made (see Annex 6).

7. Decision on scope, approach and membership

Biosecurity Australia considers submissions received from stakeholders and will hold discussions with stakeholders when the nature of matters raised in submissions makes it appropriate. The Executive Manager of Biosecurity Australia then decides the scope for the IRA, and membership of the IRA team, identifying the issues raised by stakeholders and the manner in which they have been addressed. Biosecurity Australia advises registered stakeholders of the outcome (including the reasons for decisions), and places the information on the Biosecurity Australia website and a copy of the decision on the public file.

8. Provision for stakeholder appeal

A stakeholder may appeal to a Deputy Secretary of AFFA against the Executive Manager's decision on the scope, approach and IRA team membership within 15 days of its publication. In lodging an appeal, stakeholders must give reasons for their appeal. Receipt of appeals will be acknowledged.

Matters taken into account in considering an appeal are given in Annex 3.

9. Determination of appeal

The Deputy Secretary of AFFA considers the appeal, makes a determination and notifies the appellant(s) within 45 days of the closing date for appeals. The determination includes reasons.

If an appeal is allowed, the IRA returns to step 5 (above) in respect to those issues for which the appeal was allowed. If the appeal is disallowed, the IRA team will commence work on the IRA.

Biosecurity Australia communicates the outcome of the appeal to registered stakeholders, and the information is placed on the Biosecurity Australia website and the public file.

Risk assessment

10. Initial work

After an IRA team is established, it liaises with the proponent/applicant about the technical information needed to enable an IRA to proceed. If there is insufficient information, the IRA may be delayed until the information is received.

The IRA team commences work by:

- determining a work program for the IRA
- establishing a risk communication strategy, including identifying relevant stakeholder groups
- preparing a technical issues paper.

The technical issues paper:

- summarises background and administrative matters pertaining to the IRA
- lists the pests and diseases that the IRA team has identified as being potentially associated with the importation of the goods
- categorises the pests and diseases (in some cases in a preliminary manner) according to whether they need to be considered in the subsequent risk assessment.

The technical issues paper may also include

- an outline of the additional tasks identified at that stage, e.g. for technical working groups (TWGs) and consultants
- a list of potential independent peer reviewers.

Pests and diseases are categorised conservatively. If there is doubt about their biosecurity significance, they are included for risk assessment.

The IRA team may also commission, as appropriate, consultancies and TWGs to examine and report on specific technical or economic issues.

11. Consultation on the technical issues paper

Biosecurity Australia distributes the technical issues paper to registered stakeholders and places it on the Biosecurity Australia website. Stakeholders have 60 days to submit comments. This is the first formal request for detailed technical input into the IRA. Submissions will be sought on:

- the completeness of the list of pests and disease agents and their categorisation
- the list of potential independent peer reviewers
- any additional work identified.

The IRA team may meet with stakeholders to discuss matters raised in submissions, if appropriate.

Submissions received (unless otherwise requested), are placed on the public file, as are the IRA team's response to the issues raised.

The team may conduct field trips to relevant regions, in Australia and/or potential source areas to investigate trading patterns, industry practices and procedures relevant to the assessment of risk.

12. Preparation of Draft IRA Report

The IRA team, on the basis of its research, and using input from TWGs and consultants as necessary, prepares a Draft IRA Report, taking into account submissions received on the technical issues paper and other input derived through consultation with stakeholders. As at other stages, relevant State and Territory agencies are consulted on regional pest status and risk issues.

The draft report:

- confirms the pests and diseases being assessed
- describes the major pathways by which these could enter, establish or spread in Australia
- identifies, for each pest and disease on individual pathways, the likelihood of its entry, establishment or spread, and the harm (consequences) that would result
- specifies whether the resulting risks require mitigation (i.e., to bring risk within Australia's ALOP)
- in cases where the risks are rated as unacceptable, presents an evaluation of technically-feasible risk management measures to determine whether the risk can be successfully mitigated to achieve Australia's ALOP
- includes a preliminary view of the appropriate risk management options.

13. Consultation with stakeholders on Draft IRA Report

Biosecurity Australia distributes the Draft IRA Report to stakeholders and places it on the Biosecurity Australia website. Stakeholders have 60 days to submit comments. The IRA team may meet with stakeholders to discuss the draft report.

Submissions received are placed on the public file unless a request for confidentiality is made.

14. Notification to WTO

When the Draft IRA Report is distributed to stakeholders, Biosecurity Australia's practice is to notify the WTO under the established procedures. The notification includes advice on the time by which comments should reach Biosecurity Australia.

15. Independent peer review

Before finalising either the draft or the Final IRA Report, the IRA team may seek advice from independent peer reviewers.

Reporting

16. Preparation of Final IRA Report

The IRA team, with input from TWGs and consultants as necessary, prepares a Final IRA Report. They consider submissions received on the draft into account and consult with stakeholders and the peer reviewers as appropriate.

If new information comes to light that may significantly affect the analysis, or if the IRA team identifies the need to make significant changes to the analysis in finalising the IRA Report, the IRA team, in consultation with the Executive Manager of Biosecurity Australia, may consider whether it would be appropriate to prepare a revised Draft IRA Report for stakeholder consultation. In this case, Biosecurity Australia distributes the revised Draft IRA Report to stakeholders and places it on the Biosecurity Australia website. Stakeholders are given 60 days to submit comments.

The Final IRA Report draws all issues together and includes:

- the IRA team's responses to the issues raised
- an inventory of any significant changes to the Draft IRA Report, with reasons for those changes
- information on the issues raised by independent peer reviewers and the IRA team's responses
- recommendations on the appropriate risk management options.

17. Consideration of Final IRA Report

The IRA team presents the Final IRA Report to the Executive Manager of Biosecurity Australia.

In considering the recommendations in the Final IRA Report, the Executive Manager of Biosecurity Australia must be satisfied that the IRA has been conducted in accordance with the process described in the handbook, and the recommendations:

- are reasonable in the light of the evidence

- meet the Government's objectives for biosecurity
- are consistent with Australian legislation
- accord with Australia's international rights and obligations.

The Executive Manager of Biosecurity Australia may refer the report to the IRA team for further consideration, if this is deemed necessary.

18. Consultation with States and Territories

Biosecurity Australia consults the chief executive officers of relevant State and Territory agencies on the proposed outcomes of the IRA, including regional pest status and risk issues, and aspects of joint responsibility arising from the IRA team's recommendations.

The Executive Manager of Biosecurity Australia may refer the report to the IRA Team for further consideration if this is deemed necessary as the result of this consultation.

19. Release of Final IRA Report and recommendation for a policy determination

In releasing the Final IRA Report and recommending a policy determination, which will set the parameters for import, the Executive Manager of Biosecurity Australia takes into account:

- the recommendations of the IRA team
- outcomes of discussions with the relevant State and Territory chief executive officers
- Australian legislative requirements
- international obligations
- any other relevant information or consideration.

Biosecurity Australia distributes the Final IRA Report and the recommendation for a policy determination to the proponent/applicant and registered stakeholders. The Report and recommendations are placed on the Biosecurity Australia website and on the public file, and is notified in *Biosecurity Australia News*.

20. Provision for appeals on Final IRA Report

Stakeholders are given 30 days from the publication of the recommendation for a policy determination to lodge an appeal in writing with the Import Risk Analysis Appeals Panel (IRAAP)— a body independent from Biosecurity Australia—on one or both of the following grounds:

- there was a significant deviation from the process set out in the Import Risk Analysis Handbook that adversely affected the interests of a stakeholder
- a significant body of scientific information relevant to the outcome of the IRA was not considered.

In lodging appeals, stakeholders must give reasons for their appeal.

The terms of reference for the IRAAP are at Annex 4.

If there are no appeals within 30 days, the process is complete and the recommended policy will be submitted to the Director of Animal and Plant Quarantine for determination.

21. Appeal determination

The IRAAP will consider any appeal and report its findings to the appellant(s) and the Director of Animal and Plant Quarantine within 45 days of the closing date for appeals.

If the appeal is disallowed, the process is complete.

If an appeal is allowed, the IRAAP may advise the Executive Manager of Biosecurity Australia on how to overcome the identified deficiencies. This may involve minor amendments to the Final IRA Report, significant revision or further stakeholder consultation. The Executive Manager of Biosecurity Australia considers any advice from the IRAAP in deciding how to proceed. The Executive Manager of Biosecurity Australia advises the appellant(s) and the IRAAP of the outcomes of further work undertaken to address deficiencies. This information is also placed on the Biosecurity Australia website and on the public file.

Final policy determination

22. Notification of final policy determination

When the above processes are complete, the Director of Animal and Plant Quarantine makes the final policy determination.

Biosecurity Australia notifies the proponent/applicant, registered stakeholders and the WTO of the final policy determination.

The Final IRA Report, the policy determination, the outcomes of any appeals and Biosecurity Australia's responses to issues raised, are provided to the proponent/applicant and registered stakeholders, and placed on the Biosecurity Australia website and on the public file. Information on the final policy determination is also published in *Biosecurity Australia News*.

Biosecurity Australia notifies AQIS of the new policy and liaises with AQIS on implementation.

Annex 1: Contact information

Executive Manager Biosecurity Australia, and the appeals address

Postal address: Biosecurity Australia
GPO Box 858
CANBERRA ACT 2601
AUSTRALIA

Telephone +61 2 6272 5584

Facsimile: +61 2 6272 3307

E-mail: biosecurityaustralia@affa.gov.au

Street address: Edmund Barton Building
Broughton Street
BARTON ACT 2600
AUSTRALIA

Animal Biosecurity import risk analyses

Postal address: Animal Secretariat
Animal Biosecurity
Biosecurity Australia
GPO Box 858
CANBERRA ACT 2601
AUSTRALIA

Telephone +61 2 6272 4436

Facsimile: +61 2 6272 3399

E-mail: animalbiosecurity@affa.gov.au

Street address: Edmund Barton Building
Broughton Street
BARTON ACT 2600
AUSTRALIA

Plant Biosecurity import risk analyses

Postal address: Technical and Administrative Services
Plant Biosecurity
Biosecurity Australia
GPO Box 858
CANBERRA ACT 2601
AUSTRALIA

Telephone +61 2 6272 5094

Facsimile: +61 2 6272 3307

E-mail: plantbiosec@affa.gov.au

Street address: Edmund Barton Building
Broughton Street
BARTON ACT 2600
AUSTRALIA

Agriculture Fisheries and Forestry – Australia

Postal address: Agriculture Fisheries and Forestry – Australia
GPO Box 858
CANBERRA ACT 2601
AUSTRALIA

Telephone: +61 2 6272 3933

Street address: Edmund Barton Building
Broughton Street
BARTON ACT 2600
AUSTRALIA

Annex 2: Import risk analysis team

A team of experts conducts import risk analyses. The outcome of the IRA team's work is a Final IRA Report containing recommendations for consideration by the Executive Manager of Biosecurity Australia.

Terms of reference

The standard terms of reference for an IRA team are to:

- develop the work program for the IRA
- establish a risk communication strategy
- determine whether technical working groups (TWGs), and/or consultants will be required to collate information, conduct research, undertake assessments (technical, environmental, economic) or otherwise, or to assist the IRA team on specific issues; and, if so, determine their terms of reference and oversee their work
- consult as appropriate to obtain a full and accurate understanding of the relevant issues
- use internal and independent peer review if appropriate in preparing papers and reports
- take appropriate account of Australia's ALOP and quarantine legislation, and Australia's rights and obligations
- consider stakeholder submissions in preparing papers and reports
- produce a technical issues paper for consultation
- produce a Draft IRA Report for consultation
- produce other papers and reports as necessary for efficient conduct of the IRA
- produce a Final IRA Report for consideration by the Executive Manager of Biosecurity Australia
- provide additional advice and information as requested by the Executive Manager of Biosecurity Australia.

Membership

The IRA teams vary in numbers, depending on expertise required. Team members collectively provide an appropriate combination of experience and expertise in:

- risk analysis as it relates to biosecurity
- science and regulation
- animal and/or plant pests and diseases
- industry and/or commercial processes and practices
- other disciplines relevant to the proposal or application under consideration.

Membership depends on whether the required technical expertise is available in Biosecurity Australia. Biosecurity Australia sources outside expertise as required. Such expertise may be drawn from other government agencies (Commonwealth, State and Territory), industry, scientific organisations, academia, private consultants and the general public.

A senior officer from Biosecurity Australia or a related group in AFFA chairs the IRA team. The Chair has experience in biosecurity policy, and a sound knowledge and understanding of Australian quarantine legislation, the Government's objectives for biosecurity, and Australia's international rights and obligations. Biosecurity Australia provides administrative and secretarial support.

In finalising IRA team membership, Biosecurity Australia assesses prospective team members against the following criteria:

- experience and expertise relevant to the import proposal under consideration
- proven capacity in a relevant scientific field
- knowledge of government processes and the national and international context of the IRA
- absence of conflict of interest; it being essential that:
  - prospective external team members do not, and are perceived not to, have a conflict of interest
  - they declare that their sources of income and/or representational responsibilities and/or personal or other interests do not compromise their capacity to provide impartial and independent advice
- any other consideration relevant to particular circumstances of the IRA.

If, in the course of an IRA, an external member of the IRA team ceases to be available, or if for another reason the Executive Manager of Biosecurity Australia believes it is necessary to change the membership of the IRA team, the Executive Manager may decide, in consultation with key stakeholders, to make such changes as are appropriate to ensure that the work of the IRA can be satisfactorily completed. In this event, stakeholders will be advised of the changes at the next consultation step.

Operating procedures

The IRA team conducts the IRA with support from Biosecurity Australia as needed. Biosecurity Australia produces papers and reports, and circulates these reports to stakeholders.

The IRA team operates within the operational and financial constraints of Biosecurity Australia. Biosecurity Australia, in consultation with the IRA team, agrees on a budget and the resources needed to conduct the work program efficiently. The agreed budget covers such items as meetings of the IRA team, research, members' costs for face-to-face meetings with stakeholders and publications. The budget may need to be reviewed and adjusted as work progresses.

Biosecurity Australia contracts external members for the duration of the IRA in accordance with government financial guidelines.

The IRA team determines whether additional work will be required and the most effective method of carrying out that work, for example by TWGs and/or consultants. In deciding to use TWGs or in commissioning consultancies, the IRA team takes into account resource and time constraints, and relative cost effectiveness.

Each TWG has a Biosecurity Australia member with knowledge of risk analysis techniques and the context in which the risk analysis is being conducted.

Annex 3: Appeal to Deputy Secretary

Stakeholders may appeal to the Deputy Secretary of AFFA against the decision of the Executive Manager of Biosecurity Australia on the proposed scope and approach of the IRA and the required expertise, including membership of the IRA team. The appeal must be made within 15 days of the publication of the decision. In lodging an appeal, stakeholders must give reasons for their appeal.

The Deputy Secretary of AFFA considers the appeal, makes a determination and notifies the appellant(s) within 45 days of the closing date for appeals.

Contact details

Import Risk Analysis Appeals
Deputy Secretary
Agriculture, Fisheries and Forestry – Australia
GPO Box 858
CANBERRA ACT 2601

Matters the Deputy Secretary will take into account

In making a determination on the appeal, the Deputy Secretary considers:

- whether the scope of the IRA is reasonable (with regard to the proposal or application, and any current related work) and is an efficient use of public resources
- whether the nominated IRA team membership will provide appropriate expertise
- Australian legislation and Government policies
- Australia's rights and obligations as a Member of the WTO
- any other matter that the Deputy Secretary may consider relevant.

Annex 4: Import Risk Analysis Appeal Panel

The Chair of the Import Risk Analysis Appeal Panel convenes the IRAAP when an appeal is received that provides prima facie evidence that there has been a material deficiency or failure falling within the IRAAP's terms of reference. Stakeholders have 30 days from the publication of the recommendation for a policy determination to lodge an appeal in writing.

The Chair advises the appellant(s) and the Executive Manager, Biosecurity Australia through the IRAAP Secretariat of the Chair's decision on whether the appeal warrants consideration by the IRAAP. If consideration is warranted, the proponent of the import proposal is also advised.

Contact details

The IRAAP Secretariat, which is provided by AFFA but is not part of Biosecurity Australia, coordinates all IRAAP activities and handles all correspondence.

Appeals should be made to:

The Manager
IRAAP Secretariat
Agriculture, Fisheries and Forestry – Australia
GPO Box 858
CANBERRA ACT 2601

Facsimile: +61 2 6272 4600

E-mail: IRAAP@affa.gov.au

Grounds for appeal

The IRAAP considers appeals, supported by a statement of reasons, based on one or both of the following grounds:

- there was a significant deviation from the process set out in the Import Risk Analysis Handbook that adversely affected the interests of a stakeholder
- a significant body of scientific information relevant to the outcome of the IRA was not considered.

The IRAAP does not consider matters relating to:

- issues falling within the ambit of the appeal in step 8 (see Section 4) of the Import Risk Analysis Handbook
- the scientific merits of the IRA, other than in relation to a claim that a significant body of scientific information was not considered

- the merits of the risk management recommendations made by an IRA team or of the risk management conclusions reached by Biosecurity Australia.

If new information relevant to the IRA is produced during the appeal process, the IRAAP may refer the information to the Executive Manager of Biosecurity Australia.

Membership

The IRAAP routinely comprises four members:

- Chair of Quarantine and Exports Advisory Council (Chair)
- Commonwealth Chief Veterinary Officer (CVO) / Chief Plant Protection Officer (CPPO) – chosen according to the subject of the IRA)
- an officer from AFFA (from outside Biosecurity Australia)
- one other member of QEAC (nominated by the Chair).

The Chair of QEAC, the CVO/CPPO or any other member of the IRAAP may nominate alternative members if they believe there may be a conflict of interest or perception of bias because they have been directly or indirectly involved in the IRA under appeal. Each IRAAP member is required to declare that their sources of income and/or representational responsibilities and/or personal and other interests would not prevent them from providing impartial and independent advice.

Every effort is made to have the full IRAAP membership (or their alternatives) meet in person to consider an appeal to ensure a balanced discussion.

Operating procedures

When the Chair of the IRAAP decides that evidence presented by the appellant(s) warrants consideration by the IRAAP, the Chair consults with the Director of Animal and Plant Quarantine on:

- scope and timetable of the appeal
- IRAAP membership regarding, for example, issues of conflict of interest
- the likely need for access to particular expertise for appeals concerning whether a significant body of scientific or technical information relevant to the outcome of the IRA had not been considered.

The IRAAP considers the appeal in the context of either or both of the criteria for the appeal, and reports its findings to the appellant(s) and the Director of Animal and Plant Quarantine, within 45 days of the closing date for appeals. The appellant(s) is advised if the IRAAP is unable to finalise the appeal within the 45 days.

The IRAAP does not consider verbal submissions from any appellant unless they are determined by the IRAAP to be necessary to complement an appellant's written submission.

Upholding of an appeal requires majority support. The Chair does not exercise a casting vote.

If the appeal is allowed, the IRAAP may offer advice to the Executive Manager, Biosecurity Australia, on ways of overcoming the identified deficiencies. This may involve minor amendments to the Final IRA Report, or significant revision warranting further stakeholder consultation.

Annex 5: Stakeholder register

Biosecurity Australia maintains a register of stakeholders to facilitate consultation and communication. A stakeholder is a government agency, individual person, community or industry group or organisation, whether in Australia or overseas, that has an interest in the subject matter of an IRA, including the proponent/applicant for a specific proposal.

Interested parties wishing to be included in communications and consultation on a particular proposal or application, or generally, should complete and return a stakeholder registration form to Biosecurity Australia. When a biosecurity issue is being actively considered, stakeholders listed on the register with an interest in that issue will be contacted. More than one person within an organisation may register as a stakeholder, if a separate registration form is completed for each individual.

The registration form (in Word and pdf format) may be downloaded via www.affa.gov.au/biosecurityaustralia . Completed registration forms should be mailed to:

Stakeholder Register Administrator
Biosecurity Australia
Agriculture, Fisheries and Forestry – Australia
GPO Box 858
CANBERRA ACT 2601

Facsimile: +61 2 6272 3678

E-mail: stake.holder@affa.gov.au

In the event of difficulty accessing the file in the downloadable formats, a copy can be obtained from the Stakeholder Register Administrator.

Annex 6: Public file

A public file containing non-confidential submissions and other technical documentation is established at the commencement of each IRA. Each public file is held at Biosecurity Australia's office in Canberra and documents may be accessed during business hours, by prior appointment, for perusal and copying. Submissions and other documentation in electronic form are made available to stakeholders on request. To maximise access to documents, stakeholders are encouraged to make submissions electronically. Where appropriate, documentation on the public file which is in electronic form is available on the AFFA website.

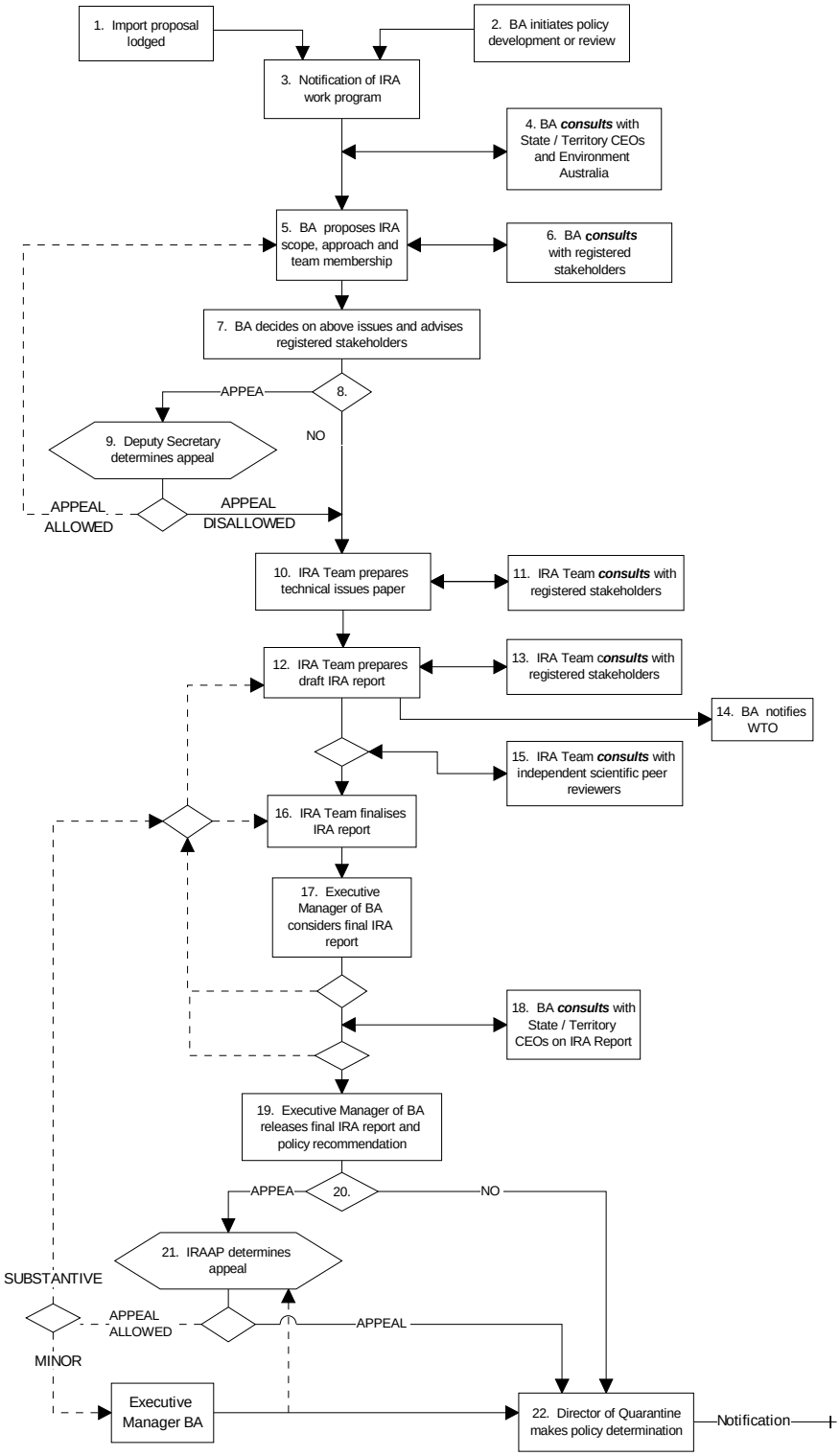
A public file for an IRA contains the following non-confidential material:

- a table of contents
- the background to the import proposal
- determinations and decisions on procedural matters made by the Deputy Secretary and the Executive Manager of Biosecurity Australia during the conduct of the IRA
- documents publicly circulated by Biosecurity Australia during the IRA, including those providing advice and/or seeking input on:
- commencement of the IRA
- scope and approach for the IRA and composition of the IRA team
- appeals
- the technical issues paper and Draft and Final IRA Reports
- the recommendation for a policy determination and the final policy determination.
- relevant technical submissions and other correspondence

  This will not include a submission, or part of a submission, that a stakeholder indicates is confidential and is capable of being classified as such in accordance with the Freedom of Information Act, or which Biosecurity Australia reasonably considers may give rise to an action for defamation.

  Advice that confidential material has been received will be placed on the public file.
- correspondence raising relevant technical issues
- technical material used in the IRA, not available in the public domain and not subject to copyright
- a list of technical material used in the IRA but subject to copyright (titles of references only)
- AFFA's responses to submissions, including statements of reasons
- where appropriate, formal reports provided by a technical working group (TWG), consultant or peer reviewer

Annex 7: Import Risk Analysis flowchart



Annex 8: Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement)

Members,
Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)[1] ;

Hereby agree as follows:

Article 1: General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.

2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.

3. The annexes are an integral part of this Agreement.

4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

Article 2: Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.

2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

Article 3: Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of

sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5[2]. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

Article 4: Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility[3].

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

Article 6: Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or

phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest-or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7: Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

Article 8: Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Article 9: Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, inter alia, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such

technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10: Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.

2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.

3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.

4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11: Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.

2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

Article 12: Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its

decisions by consensus.

2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.

3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.

4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefore, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.

6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.

7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, inter alia, to the experience gained in its implementation.

Article 13: Implementation

Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14: Final Provisions

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

Annex A: Definitions[4]

1. Sanitary or phytosanitary measure—Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

2. Harmonization —The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

3. International standards, guidelines and recommendations

(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

(b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

(c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and

(d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

4. Risk assessment—The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

5. Appropriate level of sanitary or phytosanitary protection—The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

Note: Many Members otherwise refer to this concept as the 'acceptable level of risk'.

6. Pest- or disease-free area—An area, whether all of a country, part of a country, or all or parts of several

countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

Note: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area - whether within part of a country or in a geographic region which includes parts of or all of several countries -in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. Area of low pest or disease prevalence—An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

Annex B: Transparency of Sanitary and Phytosanitary Regulations

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations[5] which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.

2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

(a) any sanitary or phytosanitary regulations adopted or proposed within its territory;

(b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;

(c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

(d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.

4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals of the Member concerned[6].

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

(a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

(b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

(c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;

(d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

(a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);

(b) provides, upon request, copies of the regulation to other Members;

(c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

7. Notifications to the Secretariat shall be in English, French or Spanish.

8. Developed country Members shall, if requested by other Members, provide copies of the documents

or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.

9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:

(a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or

(b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

Annex C: Control, Inspection and Approval Procedures[7]

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

(a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;

(b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

(c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;

(d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;

(e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;

(f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;

(g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;

(h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and

(i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

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[1] In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

[2] For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

[3] For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

[4] For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

[5] Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

[6] When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

[7] Control, inspection and approval procedures include, inter alia, procedures for sampling, testing and certification.

Annex 9: Acronyms and definitions

AFFA	Department of Agriculture, Fisheries and Forestry – Australia
appropriate level of protection (ALOP)	The level of protection deemed appropriate by a country establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory (according to Annex A of the SPS Agreement). This is also known as the acceptable level of risk.
AQIS	Australian Quarantine and Inspection Service
biosecurity	The prevention of the entry, establishment or spread of unwanted pests and infectious disease agents in people, animals, plants or the environment
Biosecurity Australia (BA)	An operating group in AFFA, responsible for the development of Australia's biosecurity policy
good	Article of trade, also "goods"
CPPO	Chief Plant Protection Officer
CVO	Chief Veterinary Officer
Director of Animal and Plant Quarantine	Secretary of AFFA, who has decision-making power under the *Quarantine Act 1908*
Environment Australia	Department of the Environment and Heritage
Executive Manager of Biosecurity Australia	Officer in charge of Biosecurity Australia
FSANZ	Food Standards Australia New Zealand
import risk analysis	The discipline through which major biosecurity policy is developed and reviewed; import risk analysis incorporates risk assessment, risk management and risk communication.
IPPC	International Plant Protection Convention
IRA	Import Risk Analysis

IRA team	A group of experts, led by an officer from Biosecurity Australia, that conducts the IRA.
IRAAP	Import Risk Analysis Appeal Panel
MAB	Market Access and Biosecurity, a business group in AFFA that includes Biosecurity Australia
MOU	Memorandum of Understanding
PISC	Primary Industries Standing Committee, comprising relevant Commonwealth, State and Territory ministers
OIE	Office International des Epizooties (World Organisation for Animal Health)
Quarantine and Exports Advisory Council (QEAC)	A ministerially appointed council that advises the Director of Animal and Plant Quarantine and the Minister
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
stakeholders	Government agencies, individual people, community or industry groups or organisations, whether in Australia or overseas, that have an interest in the subject matter of an IRA, including the proponent/applicant for a specific proposal.
TBT Agreement	WTO Agreement on Technical Barriers to Trade
TWG	technical working group
WHO	World Health Organization of the United Nations
WTO	World Trade Organization